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Amendments to the Claims:

This listing of claims will replace all prior versions, and listings, of claims in the application:

1. (Amended) A pharmaceutical composition comprising the hydrochloride salt of N-[(1-ⁿbutyl-4-piperidiny)lmethyl]-3,4-dihydro-2H-[1,3]oxazino[3,2-a]indole-10-carboxamide in combination with one or more pharmaceutically acceptable carriers, wherein at least some of the N-[(1-ⁿbutyl-4-piperidiny)lmethyl]-3,4-dihydro-2H-[1,3]oxazino[3,2-a]indole-10-carboxamide hydrochloride salt is in granulated form,
and wherein the N-[(1-ⁿbutyl-4-piperidiny)lmethyl]-3,4-dihydro-2H-[1,3]oxazino[3,2-a]indole-10-carboxamide hydrochloride salt is present in the composition in at least 4 weight % by weight of the composition.
2. (Amended) A composition as claimed in claim 1 wherein substantially all of the N-[(1-ⁿbutyl-4-piperidiny)lmethyl]-3,4-dihydro-2H-[1,3]oxazino[3,2-a]indole-10-carboxamide hydrochloride salt is in granulated form.
3. (Amended) A composition as claimed in claim 1 wherein 50% or more by weight or by volume of the granules including the N-[(1-ⁿbutyl-4-piperidiny)lmethyl]-3,4-dihydro-2H-[1,3]oxazino[3,2-a]indole-10-carboxamide hydrochloride salt have a particle size of ≥ 100 microns.
4. (Amended) A composition as claimed in claim 1 wherein 50% or more by weight or by volume of the granules including the N-[(1-ⁿbutyl-4-piperidiny)lmethyl]-3,4-dihydro-2H-[1,3]oxazino[3,2-a]indole-10-carboxamide hydrochloride salt have a particle size of ≥ 250 microns.
5. (Amended) A composition as claimed in claim 1 wherein 50% or more by weight or by volume of the granules including the N-[(1-ⁿbutyl-4-piperidiny)lmethyl]-3,4-dihydro-2H-[1,3]oxazino[3,2-a]indole-10-carboxamide hydrochloride salt have a particle size of 100 to 1000 microns.

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6. (Amended) A composition as claimed in claim 1 wherein 90% or more by weight or by volume of the granules including the N-[(1-ⁿbutyl-4-piperidiny)lmethyl]-3,4-dihydro-2H-[1,3]oxazino[3,2-a]indole-10-carboxamide hydrochloride salt have a particle size of ≥ 10 microns.
7. (Amended) A composition as claimed in claim 1 wherein 90% or more by weight or by volume of the granules including the N-[(1-ⁿbutyl-4-piperidiny)lmethyl]-3,4-dihydro-2H-[1,3]oxazino[3,2-a]indole-10-carboxamide hydrochloride salt have a particle size of ≥ 50 microns.
8. (Amended) A composition as claimed in claim 1 wherein 50% or more by weight or by volume of the particles of the N-[(1-ⁿbutyl-4-piperidiny)lmethyl]-3,4-dihydro-2H-[1,3]oxazino[3,2-a]indole-10-carboxamide hydrochloride salt have a particle size of ≤ 50 microns.
9. (Amended) A composition as claimed in claim 1 wherein 10% or more by weight or by volume of the particles of the N-[(1-ⁿbutyl-4-piperidiny)lmethyl]-3,4-dihydro-2H-[1,3]oxazino[3,2-a]indole-10-carboxamide hydrochloride salt have a particle size of ≤ 10 microns.
10. (Amended) A composition as claimed in claim 1 wherein 50% or more by weight or by volume of the granules including the N-[(1-ⁿbutyl-4-piperidiny)lmethyl]-3,4-dihydro-2H-[1,3]oxazino[3,2-a]indole-10-carboxamide hydrochloride salt have a particle size of ≥ 100 microns (micrometres); and wherein 10% or more by weight or by volume of the particles of the N-[(1-ⁿbutyl-4-piperidiny)lmethyl]-3,4-dihydro-2H-[1,3]oxazino[3,2-a]indole-10-carboxamide hydrochloride salt have a particle size of ≤ 10 microns.
11. (Amended) A composition as claimed in claim 1 wherein the N-[(1-ⁿbutyl-4-piperidiny)lmethyl]-3,4-dihydro-2H-[1,3]oxazino[3,2-a]indole-10-carboxamide hydrochloride salt is present in the composition in at least 5 weight % by weight of the composition.
12. (Amended) A composition as claimed in claim 1 wherein the N-[(1-ⁿbutyl-4-piperidiny)lmethyl]-3,4-dihydro-2H-[1,3]oxazino[3,2-a]indole-10-carboxamide hydrochloride salt is present in the composition in at least 6 weight % by weight of the composition.

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13. (Amended) A composition as claimed in claim 1 wherein the hydrochloride salt of N-[(1-ⁿbutyl-4-piperidiny)lmethyl]-3,4-dihydro-2H-[1,3]oxazino[3,2-a]indole-10-carboxamide is of a form obtainable by a process in which the N-[(1-ⁿbutyl-4-piperidiny)lmethyl]-3,4-dihydro-2H-[1,3]oxazino[3,2-a]indole-10-carboxamide hydrochloride salt is dissolved in ethanol or an ethanol-containing solvent to form a solution and is crystallised from the solution by addition of a C₅-C₁₀ hydrocarbon and/or a solvent containing a C₅-C₁₀ hydrocarbon.
14. (Amended) A composition as claimed in claim 1 wherein the granules containing the N-[(1-ⁿbutyl-4-piperidiny)lmethyl]-3,4-dihydro-2H-[1,3]oxazino[3,2-a]indole-10-carboxamide hydrochloride salt also contain a filler/diluent.
15. (Amended) A composition as claimed in claim 14 wherein the filler/diluent is abrasive.
16. (Amended) A composition as claimed in claim 14 wherein the filler/diluent is insoluble, practically insoluble, very slightly soluble or slightly soluble in water and/or ethanol.
17. (Amended) A composition as claimed in claim 14 wherein the filler/diluent is insoluble or practically insoluble in water and/or ethanol.
18. (Amended) A composition as claimed in claim 14 wherein the filler comprises any pharmaceutically acceptable metal salt which is insoluble, practically insoluble, very slightly soluble or slightly soluble in water and/or ethanol.
19. (Amended) A composition as claimed in claim 1 wherein the granules containing the N-[(1-ⁿbutyl-4-piperidiny)lmethyl]-3,4-dihydro-2H-[1,3]oxazino[3,2-a]indole-10-carboxamide hydrochloride salt also contain a filler/diluent comprising CaHPO₄ and/or Ca₃(PO₄)₂.
20. (Amended) A composition as claimed in claim 19, wherein the weight ratio of the filler to drug in the granules is at least 1:3, and wherein the filler is present in ≥ 15 weight % of the composition.
21. (Amended) A composition as claimed in claim 16, wherein the filler is present in from 15 to 85% by weight of the composition.

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22. (Amended) A composition as claimed in claim 16 including a binder present in about 1 to about 10 weight % of the composition, and wherein the binder is soluble, freely soluble or very soluble in water.
23. (Amended) A composition as claimed in claim 22 wherein the binder comprises hydroxypropylmethylcellulose, hydroxypropylcellulose, hydroxyethylcellulose, hydroxymethylcellulose, methyl cellulose, ethyl cellulose, or povidone.
24. (Amended) A composition as claimed in claim 1, 3 or 19 including an excipient which acts as a compression and/or granulation aid.
25. (Amended) A composition as claimed in claim 1 being a tablet, or a capsule containing said composition.
26. (Amended) A method of making a pharmaceutical composition comprising the hydrochloride salt of N-[(1-ⁿbutyl-4-piperidiny)methyl]-3,4-dihydro-2H-[1,3]oxazino[3,2-a]indole-10-carboxamide in combination with one or more pharmaceutically acceptable carriers, wherein the N-[(1-ⁿbutyl-4-piperidiny)methyl]-3,4-dihydro-2H-[1,3]oxazino[3,2-a]indole-10-carboxamide hydrochloride salt is present in the composition in at least 4 weight % by weight of the composition,
the method comprising forming at least some of the N-[(1-ⁿbutyl-4-piperidiny)methyl]-3,4-dihydro-2H-[1,3]oxazino[3,2-a]indole-10-carboxamide hydrochloride salt into granules.
27. (Amended) A method as claimed in claim 26 comprising mixing some or all of the N-[(1-ⁿbutyl-4-piperidiny)methyl]-3,4-dihydro-2H-[1,3]oxazino[3,2-a]indole-10-carboxamide hydrochloride salt with a filler (diluent), and optionally a compression and/or granulation aid, before granulation.
28. (Amended) A method as claimed in claim 27 wherein the granules are formed in the presence of a granulating solvent using a wet granulation process.

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29. (Amended) A method as claimed in claim 28 wherein the filler is insoluble, practically insoluble, very slightly soluble or slightly soluble in the granulation solvent.

30. (Amended) A method as claimed in claim 29 wherein after formation the granules are milled to a particle size suitable for use in tablets or capsules.

31. (Amended) A method as claimed in claim 26 wherein, after being formed and optionally milled, the granules are mixed with other pharmaceutically acceptable excipient(s) and compressed into tablets or filled into capsules.

32. (Amended) A method of making a pharmaceutical composition comprising the hydrochloride salt of N-[(1-ⁿbutyl-4-piperidiny)methyl]-3,4-dihydro-2H-[1,3]oxazino[3,2-a]indole-10-carboxamide in combination with one or more pharmaceutically acceptable carriers, wherein the N-[(1-ⁿbutyl-4-piperidiny)methyl]-3,4-dihydro-2H-[1,3]oxazino[3,2-a]indole-10-carboxamide hydrochloride salt is present in the composition in at least 4 weight % by weight of the composition

the method comprising:

(a) dissolving the N-[(1-ⁿbutyl-4-piperidiny)methyl]-3,4-dihydro-2H-[1,3]oxazino[3,2-a]indole-10-carboxamide hydrochloride salt in ethanol or an ethanol-containing solvent to form a solution,

(b) crystallising the N-[(1-ⁿbutyl-4-piperidiny)methyl]-3,4-dihydro-2H-[1,3]oxazino[3,2-a]indole-10-carboxamide hydrochloride salt from the solution by addition of a C₅-C₁₀ hydrocarbon and/or a solvent containing a C₅-C₁₀ hydrocarbon, and

(c) forming at least some of the N-[(1-ⁿbutyl-4-piperidiny)methyl]-3,4-dihydro-2H-[1,3]oxazino[3,2-a]indole-10-carboxamide hydrochloride salt into granules.

33. (Amended) A method as claimed in claim 32 wherein 50% or more by weight or by volume of the granules including the hydrochloride salt of N-[(1-ⁿbutyl-4-piperidiny)methyl]-3,4-dihydro-2H-[1,3]oxazino[3,2-a]indole-10-carboxamide have a particle size of ≥ 100 microns.

34. (Amended) A method as claimed in claim 33 comprising the additional step after formation of the granules of (d) mixing the granules with other pharmaceutically acceptable excipient(s) and compressing into tablets or filling into capsules.

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35. (New) A composition as claimed in claim 1, wherein the HCl salt of N-[(1-ⁿbutyl-4-piperidinyl)methyl]-3,4-dihydro-2H-[1,3]oxazino[3,2-a]indole-10-carboxamide is of a form obtainable by a process in which the HCl salt is dissolved in ethanol or an ethanol-containing solvent to form a solution and is crystallised from the solution by addition of a C₅-C₁₀ hydrocarbon and/or a solvent containing a C₅-C₁₀ hydrocarbon.
36. (New) A composition as claimed in claim 1, wherein the N-[(1-ⁿbutyl-4-piperidinyl)methyl]-3,4-dihydro-2H-[1,3]oxazino[3,2-a]indole-10-carboxamide or salt thereof is present in the composition in up to 70 weight % by weight of the composition.
37. (New) A composition as claimed in claim 3, wherein the granules containing the N-[(1-ⁿbutyl-4-piperidinyl)methyl]-3,4-dihydro-2H-[1,3]oxazino[3,2-a]indole-10-carboxamide hydrochloride salt also contain a filler comprising CaHPO₄ and/or Ca₃(PO₄)₂, wherein the weight ratio of the filler to drug in the granules is at least 1:3, and wherein the filler is present in ≥ 15 weight % of the composition.
38. (New) A composition as claimed in claim 1 wherein the granules containing the N-[(1-ⁿbutyl-4-piperidinyl)methyl]-3,4-dihydro-2H-[1,3]oxazino[3,2-a]indole-10-carboxamide hydrochloride salt also contain a filler comprising CaHPO₄.2H₂O.
39. (New) A composition as claimed in claim 1 wherein the granules containing the N-[(1-ⁿbutyl-4-piperidinyl)methyl]-3,4-dihydro-2H-[1,3]oxazino[3,2-a]indole-10-carboxamide hydrochloride salt also contain a fine grade filler (diluent) being fine grade CaHPO₄ or fine grade Ca₃(PO₄)₂.
40. (New) A composition as claimed in claim 24, wherein the compression and/or granulation aid is present inside the granules of the composition.
41. (New) A composition as claimed in claim 40, wherein the compression and/or granulation aid is present in at least 15 weight % of the composition.

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42. (New) A composition as claimed in claim 41, wherein the compression and/or granulation aid is microcrystalline cellulose.
43. (New) A composition as claimed in claim 24, wherein the compression and/or granulation aid is microcrystalline cellulose.
44. (New) A composition as claimed in claim 1 or 19, wherein the composition includes a disintegrant present in about 1 to about 10 weight % of the composition and a lubricant present in about 0.2 to about 5 weight % of the composition.
45. (New) A composition as claimed in claim 42, wherein the granules containing the N-[(1- n butyl-4-piperidiny)methyl]-3,4-dihydro-2H-[1,3]oxazino[3,2-a]indole-10-carboxamide hydrochloride salt also contain a filler comprising CaHPO_4 and/or $\text{Ca}_3(\text{PO}_4)_2$, wherein the weight ratio of the filler to drug in the granules is at least 1:3, and wherein the filler is present in ≥ 15 weight % of the composition.
46. (New) A composition as claimed in claim 45, wherein the composition includes a disintegrant present in about 1 to about 10 weight % of the composition and a lubricant present in about 0.2 to about 5 weight % of the composition.
47. (New) A composition as claimed in claim 1, 3 or 19, wherein the intragranular ingredients form $\geq 70\%$ by weight of the composition.
48. (New) A composition as claimed in claim 45, wherein the intragranular ingredients form $\geq 70\%$ by weight of the composition.
49. (New) A composition as claimed in claim 1, 3, 16 or 19, wherein the granules have been formed in the presence of a granulating solvent using a wet granulation process.
50. (New) A composition as claimed in claim 45, wherein the granules have been formed in the presence of a granulating solvent using a wet granulation process.
51. (New) A method as claimed in claim 26 or 32 comprising:

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mixing some or all of the N-[(1-ⁿbutyl-4-piperidinyl)methyl]-3,4-dihydro-2H-[1,3]oxazino[3,2-a]indole-10-carboxamide hydrochloride salt with a filler (diluent) comprising CaHPO_4 and/or $\text{Ca}_3(\text{PO}_4)_2$, and with microcrystalline cellulose, before granulation,

wherein the weight ratio of the filler to drug in the granules is at least 1:3, and wherein the filler is present in ≥ 15 weight % of the composition,

and wherein the microcrystalline cellulose is present in at least 15 weight % of the composition, and the microcrystalline cellulose is present inside the granules of the composition is intragranular but does not exclude that a portion is present outside the granules.

and wherein the granules are formed in the presence of a granulating solvent using a wet granulation process.